In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 20-0381V

UNPUBLISHED

SHARON CAMPBELL, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Chief Special Master Corcoran Filed: March 9, 2022 Special Processing Unit (SPU); Ruling on Entitlement; Uncontested; Causation-In-Fact; Influenza (Flu) Vaccine; Vasovagal Syncope

John Robert Howie, Howie Law, PC, Dallas, TX, for Petitioner.

Sarah Christina Duncan, U.S. Department of Justice, Washington, DC, for Respondent.

RULING ON ENTITLEMENT[1]

On April 3, 2020, Sharon Campbell filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*[2] (the "Vaccine Act"). Petitioner alleges that she "suffer[ed] a syncopal episode resulting in a fall and subsequent fracture of her tibia and fibula" after receiving an influenza ("flu") vaccine on September 17, 2018. Petition at 1. Petitioner later filed an amended petition alleging both a Table syncope injury and, in the alternative, a cause-in-fact injury of vasovagal reaction triggered by the flu vaccine and leading to the fall and subsequent lower extremity fractures. ECF 35 at 1. The case was assigned to the Special Processing Unit of the Office of Special Masters.

[1] Because this unpublished Ruling contains a reasoned explanation for the action in this case, I am required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the Ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

I. Procedural History

After an initial status conference, Petitioner was provided with the opportunity to file additional medical records, which she did over the next several months. On September 28, 2020, Respondent filed a status report indicating interest in pursuing settlement negotiations. ECF 26. However, on January 6, 2021, Petitioner filed a status report indicating that "settlement in this case is [not] feasible" and requesting permission to retain an expert to address causation. ECF 32. I subsequently issued an order setting a deadline for Respondent's Rule 4(c) Report, but I found the request for medical experts premature. ECF 33.

On February 22, 2021, Respondent filed his Rule 4(c) Report recommending that entitlement to compensation be denied because Petitioner could not establish that she suffered a Table injury of vasovagal syncope.[3] ECF 34 at 7-8. Respondent also argued that Petitioner had not established a causation-in-fact claim. *Id*. at 8-9. Petitioner then filed an amended petition alleging both a Table syncope injury and, in the alternative, a causation-in-fact injury of "vasovagal reaction." ECF 35. The same day, Petitioner also filed a Motion for Summary Judgment with accompanying medical literature. ECF 36-37.

On May 21, 2021, Respondent filed an Amended Rule 4(c) Report and Response to Petitioner's Motion for Summary Judgment. ECF 39. In it, Respondent stated,

> [i]n light of [P]etitioner's Motion and the evidence filed therewith, and while maintaining his position that [P]etitioner's medical records do not establish that she lost consciousness as required by the QAI, . . . he will not continue to defend this case during further proceedings on entitlement before the Office of Special Masters.

Id. at 3. Respondent also requested a ruling on the record regarding Petitioner's entitlement to compensation. *Id*. Therefore, this matter is now ripe for adjudication.

[3] Specifically, Respondent noted that Petitioner's medical records consistently reflect that she did not lose consciousness after receiving the flu vaccine, which the Qualifications and Aids to Interpretation (QAI) require for a Table injury of vasovagal syncope. ECF 34 at 8. Respondent further argued that Petitioner's medical providers diagnosed her as having experienced a presyncopal or vasovagal event rather than an episode of syncope. *Id*. at 8.

II. Relevant Factual History

A. *Medical Records*

Petitioner was a 64-year-old histology specialist when she received the flu vaccine on September 17, 2018, during an outdoor flu clinic at her place of employment, Massachusetts General Hospital ("MGH"). Ex 2 at 1. Fifteen minutes after vaccination, Petitioner arrived in the MGH emergency room ("ER") reporting a "pre-syncopal episode" with "a fall down stairs after receiving her influenza vaccine." Ex 5c at 111-12. The ER physician initially assessed Petitioner with "dislocation of proximal tibia/fibula after a fall which sounds to be vaso-vagal after her influenza shot." *Id*. at 113.

Petitioner was subsequently evaluated by Dr. Marilyn Heng, an orthopedic surgeon. Ex 5c at 117. Dr. Heng's notes reflect that after Petitioner received her flu shot, she "began feeling weak while she was ambulating downstairs and she stumbled to the ground." *Id*. Dr. Heng diagnosed Petitioner with a "displaced, closed, acute fracture of the left tibial plateau" caused by "vasovagal pre-syncope leading to a fall onto her left lower extremity." *Id*. at 116-17.

On September 19, 2018, Petitioner underwent surgical open reduction and internal fixation of her left tibial plateau fracture and lateral meniscus repair. Ex 5c at 138-39. She was discharged from the hospital three days later. *Id*. at 89. Three months after surgery, Petitioner was released to WBAT,[4] and she underwent physical therapy evaluation during which she reported that "she got dizzy for a bit and fell down a flight of stairs" after receiving a flu shot. Ex 5d at 632; Ex 5e at 9.

B. *Affidavits & Other Documentation*

In her affidavit, Petitioner reports that she received the flu vaccine through her employer on September 17, 2018. Ex 1 at ¶ 4. With regard to her fall, Petitioner avers:

> Immediately after [vaccine] administration, I stood up, walked out of the tent, and walked approximately ten feet toward a nearby, concrete stairwell in the lawn.[5] Upon arriving at the top of the stairwell, I began to feel dizzy, and everything went black. The next thing I knew, I was laying on the ground at the bottom of the stairs.

[4] Weight bearing as tolerated.

[5] Petitioner's employer had erected a tent outside where employees could receive their flu vaccines. Ex 1 at ¶ 4.

Id. The record also reflects that approximately four hours after her fall, Petitioner called MGH Occupational Health Service and reported that after receiving her flu shot, she "fel[t] a little dizzy walking down the stairs to the lawn area" and fell. Ex 7 at 187.

III. Summary Judgment vs Ruling on the Record

Pursuant to Vaccine Rule 3(b)(2), special masters are responsible for "mak[ing] the proceedings expeditious, flexible, and less adversarial, while at the same time affording each party a full and fair opportunity to present its case and creating a record sufficient to allow review of the special master's decision." Under Vaccine Rule 8(d), a special master "may decide a case on the basis of written submissions without conducting an evidentiary hearing. Submissions may include a motion for summary judgement, in which event the procedures set forth in RCFC 56[6] will apply."

As I have previously observed (relying on controlling Federal Circuit precedent), "a special master's ability to decide a case based upon written submissions without a hearing is not limited to a motion for summary judgement." *Smallwood v. Sec'y of Health & Human Servs.*, No. 18-0291V, 2020 WL 2954958, at *7 (Fed. Cl. Spec. Mstr. Apr. 29, 2020) (citing *Kreizenbeck v. Sec'y of Health & Human Servs.*, 945 F.3d 1362, 1366 (Fed. Cir. 2020)). Rather, special masters may rule on the record after affording each party "a full and fair opportunity to present its case." *Kreizenbeck*, 945 F.3d at 1366 (citing Vaccine Rule 3(b)(2)).

Although Petitioner styles her present motion as one for summary judgment, I find at this stage in the proceedings (and given the extensive factual materials filed) that it is best treated as requesting a ruling on the record. The record in this case with regard to entitlement is fully developed, and the parties have been afforded a full and fair opportunity to present their evidence and arguments. In order to resolve the motion and determine if in fact Petitioner should receive a damages award, I must weigh the evidence – a task I am empowered to perform without hearing, but which goes beyond the more limited judicial determinations implicit to the summary judgment process. Accordingly, I treat Petitioner's motion as one requesting a ruling on the record, and shall evaluate the parties' positions accordingly.

[6] RCFC 56 sets forth the rules governing summary judgment. The Vaccine Rules "govern all proceedings before the United States Court of Federal Claims." Vaccine Rule 1(a). Pursuant to the Vaccine Rules, "[t]he RCFC apply only to the extent they are consistent with the Vaccine Rules." Vaccine Rule 1(c). Vaccine Rule 8(d) specifically incorporates the procedures set forth in RCFC 56 when a motion for summary judgment is filed.

IV. Applicable Law

A. *Standards for Vaccine Claims*

To receive compensation in the Vaccine Program, a petitioner must prove that: (1) they suffered an injury falling within the Vaccine Injury Table (i.e., a "Table Injury"); or (2) they suffered an injury actually caused by a vaccine (i.e., a "Non-Table Injury). *See* Sections 13(a)(1)(A), 11(c)(1), and 14(a), as amended by 42 C.F.R. § 100.3; § 11(c)(1)(C)(ii)(I); *see also Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006). To bring a successful Table claim, the petitioner must make a precise factual showing sufficient to meet the Table's relevant definitions, as set forth in the Table's "Qualifications and aids to interpretation" ("QAIs"). Section 14(b). If successful, the petitioner need not establish vaccine causation, as it is presumed if the Table requirements for a particular claim are met. Section 14(a). In this case, Petitioner asserts both a Table and non-Table claim.

For both Table and Non–Table claims, Vaccine Program petitioners bear a "preponderance of the evidence" burden of proof. Section 13(1)(a). That is, a petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly*, 592 F.3d at 1322 n.2; *see also Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (1984) (explaining that mere conjecture or speculation is insufficient under a preponderance standard). On one hand, proof of medical certainty is not required. *Bunting v. Sec'y of Health & Hum. Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). But on the other hand, a petitioner must demonstrate that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1352–53 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Human Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner may not receive a Vaccine Program award based solely on his assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. Section 13(a)(1).

In attempting to establish entitlement to a Vaccine Program award of compensation for a Non-Table claim, a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen v. Sec'y of Health and Human Servs.,* 418 F.3d 1274, 1278 (Fed. Cir. 2005): "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal

relationship between vaccination and injury." Each *Althen* prong requires a different showing and is discussed in turn along with the parties' arguments and my findings.

Under *Althen* prong one, petitioners must provide a "reputable medical theory," demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford*, 451 F.3d at 1355–56 (citations omitted). To satisfy this prong, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Human Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must only be "legally probable, not medically or scientifically certain." *Id.* at 549.

However, the Federal Circuit has *repeatedly* stated that the first prong requires a preponderant evidentiary showing. *See Boatmon v. Sec'y of Health & Human Servs.*, 941 F.3d 1351, 1360 (Fed. Cir. 2019) ("[w]e have consistently rejected theories that the vaccine only "likely caused" the injury and reiterated that a "plausible" or "possible" causal theory does not satisfy the standard"); *see also Moberly*, 592 F.3d at 1321; *Broekelschen v. Sec'y of Health & Human Servs.*, 618 F.3d 1339, 1350 (Fed. Cir. 2010). This is consistent with the petitioner's ultimate burden to establish his overall entitlement to damages by preponderant evidence. *W.C. v. Sec'y of Health & Human Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted). If a claimant must *overall* meet the preponderance standard, it is logical that they be required also to meet each individual prong with the same degree of evidentiary showing (even if the *type* of evidence offered for each is different).

Petitioners may offer a variety of individual items of evidence in support of the first *Althen* prong, and are not obligated to resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1378–79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325–26). No one "type" of evidence is required. Special masters, despite their expertise, are not empowered by statute to conclusively resolve what are essentially thorny scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Andreu,* 569 F.3d at 1380. But even though "scientific certainty" is not required to prevail, the individual items of proof offered for the "can cause" prong must *each* reflect or arise from "reputable" or "sound and reliable" medical science. *Boatmon,* 941 F.3d at 1359–60.

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375–77; *Capizzano*, 440 F.3d at 1326; *Grant v. Sec'y of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). In establishing that a

vaccine "did cause" injury, the opinions and views of the injured party's treating physicians are entitled to some weight. *Andreu*, 569 F.3d at 1367; *Capizzano*, 440 F.3d at 1326 ("medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury'") (quoting *Althen*, 418 F.3d at 1280). Medical records are generally viewed as particularly trustworthy evidence, since they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

However, medical records and/or statements of a treating physician's views do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. Section 13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y of Health & Human Servs*., 88 Fed. Cl. 706, 746 n.67 (2009) ("there is nothing . . . that mandates that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted"). Instead, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases.

The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase "medically-acceptable temporal relationship." *Id.* A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *de Bazan v. Sec'y of Health & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must also coincide with the theory of how the relevant vaccine can cause an injury (*Althen* prong one's requirement). *Id.* at 1352; *Shapiro v. Sec'y of Health & Human Servs.*, 101 Fed. Cl. 532, 542 (2011), *recons. den'd after remand*, 105 Fed. Cl. 353 (2012), *aff'd mem.*, 2013 WL 1896173 (Fed. Cir. 2013); *Koehn v. Sec'y of Health & Human Servs.*, No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for review den'd* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

B. *Law Governing Analysis of Fact Evidence*

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records. Section 11(c)(2). The special master is required to consider "all [ ] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or

autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as the "results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." Section 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Human Servs*., 3 F.3d 415, 417 (Fed. Cir. 1993) (it is within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such findings are supported by a rational determination).

As noted by the Federal Circuit, "[m]edical records, in general, warrant consideration as trustworthy evidence." *Cucuras*, 993 F.2d at 1528; *Doe/70 v. Sec'y of Health & Human Servs.*, 95 Fed. Cl. 598, 608 (2010) ("[g]iven the inconsistencies between petitioner's testimony and his contemporaneous medical records, the special master's decision to rely on petitioner's medical records was rational and consistent with applicable law"), *aff'd*, *Rickett v. Sec'y of Health & Human Servs*., 468 F. App'x 952 (Fed. Cir. 2011) (non-precedential opinion). A series of linked propositions explains why such records deserve some weight: (i) sick people visit medical professionals; (ii) sick people attempt to honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Human Servs.*, No. 11-685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013); *Cucuras*, 993 F.2d at 1525.

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Human Servs*., No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneous medical records are often found to be deserving of greater evidentiary weight than oral testimony—especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; *see also Murphy v. Sec'y of Health & Human Servs*., 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed. Cir. 1992), *cert. den'd*, *Murphy v. Sullivan*, 506 U.S. 974 (1992) (citing *United States v. United States Gypsum Co.*, 333 U.S. 364, 396 (1947) ("[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.")).

However, the Federal Circuit has also noted that there is no formal "presumption" that records are accurate or superior on their face to other forms of evidence. *Kirby v.*

Sec'y of Health & Human Servs., 997 F.3d 1378, 1383 (Fed. Cir. 2021). There are certainly situations in which compelling oral testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Human Servs*., 69 Fed. Cl. 775, 779 (2006) ("like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking"); *Lowrie*, 2005 WL 6117475, at *19 ("[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent") (quoting *Murphy*, 23 Cl. Ct. at 733)). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec'y of Health & Human Servs*., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

C. *Consideration of Medical Literature*

While I have reviewed all the medical literature submitted in this case, I discuss only those articles that are most relevant to my determination and/or are central to petitioner's case—just as I have not exhaustively discussed every individual medical record filed. *Moriarty v. Sec'y of Health & Human Servs.*, No. 2015–5072, 2016 WL 1358616, at *5 (Fed. Cir. Apr. 6, 2016) ("[w]e generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision") (citation omitted); *see also Paterek v. Sec'y of Health & Human Servs.,* 527 F. App'x 875 (Fed. Cir. 2013).

V. Analysis

A. *The Parties' Arguments*

Respondent argues that Petitioner has not established that she experienced syncope as defined by the QAI after her flu vaccine because she did not lose consciousness (although he rests his argument on the record without additional elaboration). ECF 39 at 9, 10. Petitioner maintains in response that regardless of whether she lost consciousness, "the evidence conclusively demonstrates that [she] experienced a vasovagal episode that was caused by her influenza vaccination and that resulted in a fall with permanent injuries." ECF 37 at 1.

B. *Syncope Under the Vaccine Injury Table*

Vasovagal syncope is a Table injury for the flu vaccine when it occurs within one hour of vaccine administration.[7] 42 C.F.R. § 100.3(a)XIV.C. The QAI criteria define vasovagal syncope as:

> [L]oss of consciousness (fainting) and postural tone caused by a transient decrease in blood flow to the brain occurring after the administration of an injected vaccine. Vasovagal syncope is usually a benign condition but may result in falling and injury with significant sequela. Vasovagal syncope may be preceded by symptoms such as nausea, lightheadedness, diaphoresis, and/or pallor. Vasovagal syncope may be associated with transient seizure-like activity, but recovery of orientation and consciousness generally occurs simultaneously with vasovagal syncope. Loss of consciousness resulting from the following conditions will not be considered vasovagal syncope: organic heart disease, cardiac arrhythmias, transient ischemic attacks, hyperventilation, metabolic conditions, neurological conditions, and seizures. Episodes of recurrent syncope occurring after the applicable time period are not considered to be sequela of an episode of syncope meeting the Table requirements.

42 C.F.R. § 100.3(c)(13). It is thus clear from the QAI description that proof of loss of consciousness is a fundamental factual element that must be established to meet the Table requirements.

Petitioner cannot meet these strict requirements for her Table claim, as the record clearly demonstrates that she did not experience loss of consciousness ("LOC") after vaccination. Records from the emergency department reflect that Petitioner presented with "dizziness without [LOC] leading to a mechanical fall." Ex 5c at 120, 123. Petitioner also denied LOC when she was evaluated by Dr. Heng and when she phoned Occupational Health to report her fall. *Id*. at 117; Ex 7 at 187. The notes from Petitioner's perioperative risk evaluation also reflect "[t]here appears to be no sign of actual LOC." Ex 5c at 120-21. Furthermore, Petitioner asserts in her affidavit that "[u]pon arrival in the emergency department, [she] explained to the nursing staff that [she] had received an influenza vaccination that morning, and afterwards, [she] felt woozy . . . and fell." Ex 1 at ¶ 5. Petitioner also avers she "began feeling weak" and "developed dizziness" while walking down the stairs after vaccination. *Id*. at ¶¶ 6-7, 14. In the absence of any evidence

[7] Respondent does not contest that Petitioner's fall occurred within one hour of vaccination. ECF 39 at 8 n.5.

of LOC, Petitioner's cannot establish by preponderant evidence that she suffered a Table injury of vasovagal syncope.[8] Accordingly, Petitioner's Table claim is dismissed.

C. *Causation-in-Fact*

In her amended petition, Petitioner also alleges a "vasovagal reaction" caused-in-fact by her flu vaccine resulting in her fall and left lower extremity injuries. ECF 35 at 1. Because a "vasovagal reaction" is not a Table injury, there is no causal presumption available for this alternative claim. However, when alleging a non-Table injury, a petitioner is also not bound by the narrow criteria enumerated in the QAI.

1. *Althen* Prong 1

Petitioner's burden under the first *Althen* prong is to provide "a medical theory causally connecting the vaccination and the injury." *Althen*, 418 F.3d at 1278. In this case, Petitioner argues that the flu vaccination could cause a vasovagal event that, even if it did not itself involve a loss of consciousness, could impact an individual sufficiently to precipitate a fall (as is alleged to have occurred here). ECF 37 at 8.

In making this assertion, Petitioner relies on medical literature describing the pathophysiology of vasovagal syncope, which results from a loss of blood perfusion in the brain that can be brought about by nervous system stimulation, often in a setting of fear or emotional stress. M. Braun et al., *Syncope After Immunization*, 151 Archives Pediatric Adolescent Med. 255 (1997), filed as Ex 16 on April 19, 2021 (ECF 36-3) ("Braun"). Vasovagal reactions are "known to be elicited by a variety of stimuli including simple venipuncture." Braun at 255. Furthermore, "syncopal episode[s] (vasovagal, faint) [can] occur due to a . . . painful stimulus (e.g., vaccination)," a common and well-described trigger. N. Crawford et al., *Syncope & Seizures Following Human Papillomavirus Vaccination: A Retrospective Case Series*, 194 Med. J. Austl. 16 (2011), filed as Ex 20 on April 19, 2021 (ECF 36-7) ("Crawford").

More specifically, in the initial phase (during the response to the "threat"), stimulation of the sympathetic nervous system causes anxiety, accompanied by a rapid heart rate and rising blood pressure. D. Graham et al., *Vasovagal Fainting: A Diphasic Response*, XXIII:6 Psychosomatic Med. 493 (1961), filed as Ex 18 on April 19, 2021 (ECF 36-5) ("Graham"); P. Gilchrist & B. Ditto, *The Effects of Blood-Draw & Injection Stimuli on the Vasovagal Response*, 49:6 Psychophysiology 815 (2012), filed as Ex 19 on April 19,

[8] *Accord Kidwell v. Sec'y of Health & Human Servs.*, No. 17-0651V, 2021 WL 4203056, at *13-14 (Fed. Cl. Spec. Mstr. Aug. 19, 2021) (finding that the petitioner could not satisfy the Table syncope injury requirements because she did not lose consciousness).

2021 (ECF 36-6); Braun at 255; Crawford at 16. In the second phase (after cessation of the "threat"), there is relief from the anxiety accompanied by a fall in heart rate and blood pressure, which can result in vasovagal fainting. *Id*.

Presyncope, also known as "near syncope," is the prodrome[9] of syncope without the loss of consciousness. E. Centeno et al., *Syncope*, Clev. Clinic Ctr. for Continuing Educ. (2018), filed as Ex 22 on April 19, 2021 (ECF 36-9) ("Centeno"). Data suggest that the pathophysiology, causes, and outcomes of near syncope mimic those of syncope. J. Whitledge, *Presyncope*, Nat'l Ctr. for Biotechnology Infor. Bookshelf (2021), filed as Ex 21 on April 19, 2021 (ECF 36-8) ("Whitledge") (defining presyncope as a "feeling like one was going to pass out but without actual loss of consciousness"). Symptoms common to both presyncope and syncope include lightheadedness, weakness, nausea, palpitations, and blurry vision. Whitledge at 1.

In fact, some researchers do not even require evidence of LOC when classifying a syncopal episode. In Graham, for example, it was noted that it is "unrealistic to insist on complete loss of consciousness as a criterion of fainting, since it is clear . . . that the vasovagal faint is not an all-or-nothing reaction but occurs in various degrees." Graham at 494. Instead, for purposes of the study, a vasovagal faint was defined as "a sudden drop in blood pressure and pulse rate, accompanied by a report [from the study participant] of some disturbance of consciousness, *expressed in such words as 'dizzy,' light-headed,' and 'woozy.'*" *Id.* (emphasis added); *see also* Crawford at 17 (defining syncope as an "episode of pallor and unresponsiveness or *reduced responsiveness or feeling light-headed* and occurring while vaccine being administered or shortly thereafter (usually within 5 minutes)" (emphasis added).

Furthermore, the Institute of Medicine has concluded that evidence convincingly supports a causal relationship between injection of a vaccine and vasovagal syncope. ADVERSE EFFECTS OF VACCINES: EVIDENCE AND CAUSALITY 615, 623-24 (2012), filed as Ex 14 on April 19, 2021 (ECF 36-1). In fact, pursuant to the reports of syncopal episodes from VAERS[10] and the NVICP,[11] "the predominant cause [of syncope after vaccination] [i]s vasovagal reaction." Braun at 258. As a result, the Centers for Disease Control (CDC) recommends that "to prevent syncope-related injuries, vaccine providers should follow

[9] A premonitory symptom or precursor; a symptom indicating the onset of a disease. DORLAND'S MEDICAL DICTIONARY Online, https://www.dorlandsonline.com/dorland/definition?id=41089&searchterm=prodrome (last visited November 24, 2021).

[10] Vaccine Adverse Event Reporting System.

[11] National Vaccine Injury Compensation Program.

the ACIP[12] recommendations to strongly consider observing patients for 15 minutes after vaccination." A. Sutherland et al., Syncope After Vaccination, 57 Morbidity & Mortality Wkly. Rep. 457 (2008), filed as Ex 17 on April 19, 2021 (ECF 36-4) ("Sutherland"). And I take notice of the fact that the incorporation of vasovagal response in the Table definition of syncope serves as tacit acknowledgement by Respondent of a causal link between the two conditions.[13]

Accordingly, I find there is preponderant evidence to establish that influenza vaccination can cause a presyncopal vasovagal reaction, even in the absence of LOC. This determination is consistent with prior findings in other persuasively-reasoned decisions. *See, e.g.*, *Kidwell v. Sec'y of Health & Human Servs.*, No. 17-0651V, 2021 WL 4203056, at *14 (Fed. Cl. Spec. Mstr. Aug. 19, 2021) (finding that the flu vaccine can cause presyncope under *Althen* prong 1).[14]

2. *Althen* Prong 2

Petitioner has also preponderantly satisfied the second, "did cause," *Althen* prong. *Althen*, 418 F.3d at 1278. As discussed above, the QAI recognize that vasovagal syncope may be preceded by lightheadedness,[15] a symptom reported by Petitioner as occurring only minutes after vaccination. Ex 5c at 107, 113, 119, 120, 123-24, 129. The QAI also indicate that while vasovagal episodes are usually benign, they can "result in falling and injury with significant sequela." 42 C.F.R. § 100.3(c)(13). While I reiterate the fact that this

[12] Advisory Committee on Immunization Practices.

[13] *See C.C. v. Sec'y of Health & Hum. Servs.,* No. 17-0708V, 2021 WL 2182817, at *21 (Fed. Cl. Spec. Mstr. Mar. 31, 2021) (citing *Doe 21 v. Sec'y of Health & Hum. Servs.,* 88 Fed. Cl. 178, 199 (2009), *rev'd on other grounds*, 527 Fed. Appx. 875 (Fed. Cir. 2013)) (in non-Table cases, "a link to a Table injury can support a petitioner's ability to fulfill *Althen's* first prong"); *Lesher v. Sec'y of Health & Hum. Servs.,* No. 17-1076V, 2020 WL 4522381, at *11 (Fed. Cl. Spec. Mstr. July 2, 2020) (citing *Doe 21*, 88 Fed. Cl. at 193) (a "recognition of the causal link between vaccine and injury has been held to support the establishment of the theory require[d] by the first Althen prong, since it suggests the existence of reliable medical or scientific evidence supporting the 'can cause' prong").

[14] In reaching a decision in this case, I have considered other decisions issued by special masters involving similar injuries, vaccines, or circumstances. There is no error in doing so. Although only Federal Circuit decisions control the outcome herein (*Boatmon*, 941 F.3d at 1358-59; *Hanlon v. Sec'y of Health & Hum. Servs*., 40 Fed. Cl. 625, 630 (1998)), special masters reasonably draw upon their experience in resolving Vaccine Act claims. *Doe v. Sec'y of Health & Hum. Servs*., 76 Fed. Cl. 328, 338-39 (2007) ("[o]ne reason that proceedings are more expeditious in the hands of special masters is that the special masters have the expertise and experience to know the type of information that is most probative of a claim"). I would therefore be remiss in ignoring prior cases presenting similar theories or factual circumstances, along with the reasoning employed in reaching such decisions.

[15] 42 C.F.R. § 100.3(c)(13).

is not a Table claim, the QAI description of a comparable injury has relevance to understanding these circumstances.

In this case, the records reflect that approximately five minutes after vaccination, Petitioner was descending a flight of stairs when she felt dizzy and "took a mis-step and fell on the concrete floor." Ex 5c at 121; Ex 7 at 172. Furthermore, Petitioner's treating physicians consistently classified her episode as a vasovagal presyncopal response to the flu vaccination. *See, e.g.*, Ex 5c at 111, 113, 117, 119, 120, 123, 167. For example, the ER records reflect that Petitioner presented with a "syncopal episode leading to LLE[16] injury" after receiving her flu vaccine. Ex 5c at 107. Dr. Heng, the orthopedic surgeon, also attributed Petitioner's fall to a "pre-syncope (likely vasovagal)" episode. Ex 5c at 119. Finally, Petitioner's discharge summary further reflects that she "had a vaso-vagal fall" causing a left tibial plateau fracture. Ex 5c at 89.

In determining whether the flu vaccination caused Petitioner's injury, I have also considered whether the records demonstrate evidence of any other condition that could have resulted in her vasovagal episode.[17] Petitioner's past medical history includes hypertension; however, on her initial presentation to the ER, the evaluating physician noted there was low concern for a cardiac cause of her fall. Ex 5c at 111. Additionally, the treatment records reflect that Petitioner denied chest pain, shortness of breath, palpitations, and focal neurological changes preceding her fall, and there was "[l]ow suspicion for cardiogenic or neurologic etiology of [her] near syncope." Ex 5c at 117, 119. As a precaution, Petitioner was referred for perioperative risk evaluation, which found that Petitioner's history of "feeling well prior to getting [the] flu shot then [getting dizzy] a few minutes after . . . strongly suggests a vasovagal response to her shot." *Id*. at 119-20, 123. As Petitioner had no cardiac history and a "normal cardiac exam . . . and . . . ECG," Petitioner was determined to be at low risk of developing cardiac and pulmonary complications during surgery. *Id*. at 120-23.[18]

Overall, the evidence establishes that Petitioner experienced a "painful stimulus" (vaccination), which activated her central nervous system. Once vaccination was

[16] Left lower extremity.

[17] *See Kidwell*, 2021 WL 4203056, at *16-18.

[18] In contrast to the present case, treaters who contemporaneously evaluated the petitioner in *Kidwell* after her "episode" concluded that no syncopal (or presyncopal) process was implicated. 2021 WL 4203056, at *16-17. The *Kidwell* petitioner's ER discharge records also listed a transient ischemic attack as the most likely explanation for her symptoms. *Id*. The special master's decision further notes that the *Kidwell* petitioner's symptoms were also consistent with additional other disorders for which she had established diagnoses (e.g., bradycardia, vertigo, and a disorder of the inner ear). *Id*. at 17-18. The *Kidwell* petitioner also had a pre-existing history of syncopal episodes unrelated to vaccination. *Id*. at 18.

complete and Petitioner was released to return to work, she experienced relief from her anxiety (likely accompanied by decreased heart rate and lowered blood pressure), causing her to feel woozy, dizzy, and weak. Petitioner's treating physicians universally attributed her symptoms of wooziness, dizziness, and weakness and her subsequent fall to a presyncopal, or near syncopal, vasovagal reaction to vaccination. Ex 5c at 89, 107, 111, 113, 117, 119, 120, 123-24, 129, 167. And as noted above, presyncope occurs through the same physiologic process as syncope, with common symptoms between the two conditions. Centeno at 2-3; Whitledge at 1. There is also no other competing explanation for Petitioner's vasovagal response. Preponderant evidence supports the conclusion that the vaccine likely caused her presyncopal reaction.

3. *Althen* Prong 3

Petitioner has also provided preponderant evidence showing a proximate temporal relationship between the vaccination and injury. Petitioner fell within 15 minutes of vaccination – receiving the flu vaccine at 9:30am and then arriving at the ER by 9:45am. The medical records further document that Petitioner felt woozy, dizzy, and weak immediately preceding her fall. Given this timeline, these symptoms, which resulted in her fall, must have occurred within minutes of vaccination.

As discussed above, presyncope is a prodrome of syncope and occurs through the same pathophysiologic process as syncope, which most commonly occurs within 15 minutes of vaccination. Sutherland at 3; Centeno at 2-3; Whitledge at 1. Therefore, I find there is preponderant evidence to conclude that Petitioner's influenza vaccination resulted in a vasovagal episode only minutes after vaccination, and that such a timeframe between vaccination and onset is medically acceptable.

4. Other Entitlement Issues

Petitioner must also establish that her injuries satisfy the Vaccine Act's severity requirement. § 300aa-11(c)(1)(D). In relevant part, the Vaccine Act requires a petitioner to demonstrate that the residual effects of her injury persisted for at least six months or that her injury resulted in inpatient hospitalization and surgical intervention. *Id*. As discussed above, the medical records show that Petitioner was hospitalized for five days and underwent surgery to treat her left lower extremity fractures after her fall. Ex 5c at 89, 138-39. Petitioner also continued to suffer the residual effects of her injury for more than six months, as she underwent a third surgical revision procedure on May 29, 2019, eight months after vaccination. Ex 5g at 284-87. Accordingly, this requirement is satisfied.

5. Comment on Table's LOC requirement

Respondent often reasonably "polices" the requirements of a Table claim, since such a claim relieves petitioners of the obligation to establish causation. Thus, Respondent not only requires strict satisfaction of Table requirements (for example, refusing to concede SIRVA claims where a 48-hour onset is not established), but also resists arguments that a claimant's showing that falls just short of a Table element is nevertheless "close" enough to enjoy the Table's protective benefits. *See, e.g.*, *Greene v. Sec'y of Health & Human Servs.*, No. 11-0631V, 2019 WL 4072110 (Fed. Cl. Spec. Mstr. Aug. 2, 2019) (denying entitlement when the petitioner's brachial neuritis symptoms arose 41 days after vaccination and thus outside of the 28-day limit for a brachial neuritis Table claim), *review denied*, 164 Fed. Cl. 655 (2020), *aff'd*, 841 Fed. Appx. 195 (2020).

Here, it might appear that my determination effectively stretches the terms of a Table syncope claim, permitting Petitioner to recover despite her inability to prove LOC. But that view, while understandable, would be incorrect. Because *in this case* Petitioner has preponderantly demonstrated, with citation to persuasive items of literature, that she experienced a different *form* of syncope that is not dependent on LOC. In other matters, by contrast, the inability to meet the Table claim elements is fatal, where the existing science so plainly supports a particular element that falling "closely" outside of it means the facts of the case presented are not likely to establish what in other circumstances might be a legitimate vaccine injury. *See, e.g.*, *Rowan v. Sec'y of Health & Human Servs.*, No. 17-0760V, 2020 WL 2954954, at *19 (Fed. Cl. Spec. Mstr. Apr. 28, 2020) (petitioner's claim dismissed because she had not demonstrated that the flu vaccine could cause GBS in a 30 to 36-hour timeframe); *see also Orton v. Sec'y of Health & Human Servs.*, No. 13-631V, 2015 WL 1275459 (Fed. Cl. Spec. Mstr. Feb. 23, 2015) (claim with a one-day onset of GBS after flu vaccine dismissed). However, the inability to meet Table elements will not always mean a non-Table version of the same claim could succeed – as I have found here.

VI. Conclusion

Petitioner has preponderantly demonstrated that (1) flu vaccination can cause a vasovagal response; (2) this vasovagal response resulted in dizziness, wooziness, and weakness, causing Petitioner's fall; (3) the onset of her symptoms occurred within minutes of vaccination; and (4) her injury resulted in inpatient hospitalization and surgical intervention. Therefore, I find that Petitioner is entitled to compensation.

VII. Scheduling Order

Petitioner shall file a status report updating me on the progress made toward informally resolving the issue of damages by no later than **Friday, April 8, 2022**.[19] The status report shall indicate the date by which Petitioner provided, or intends to provide, a demand for damages to Respondent.

IT IS SO ORDERED.

s/Brian H. Corcoran
Brian H. Corcoran
Chief Special Master

[19] The parties are reminded that they should not retain a medical expert, life care planner, or other expert without consulting each other and the Chief Special Master. If counsel retains an expert without so consulting in advance, reimbursement of those costs may be affected.